

## **ACKNOWLEDGMENTS**

1. The Examiner acknowledges receipt of the amendment filed 1/18/08 wherein claims 6, 7, 25, and 26 were amended and claim 8 was canceled.

**Note:** Claims 1-7 and 9-26 are pending.

## **WITHDRAWN CLAIMS**

2. Claims 1-5 and 10-24 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention/species.

## **RESPONSE TO APPLICANT'S ARGUMENTS/AMENDMENT**

3. The Applicant's arguments and/or amendment filed 1/18/08 to the rejection of claims 6, 7, 9, 25, and 26 made by the Examiner under 35 USC 103 and/or 112 have been fully considered and deemed persuasive-in-part for the reasons set forth below.

### **112 Second Paragraph Rejections**

The 112 rejections are WITHDRAWN because Applicant has amended the claims to overcome the rejections

### **103 Rejections**

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

I. The rejection of claims 6, 7, 9, 25, and 26 under 35 U.S.C. 103(a) as being unpatentable over Patel et al (US Patent No. 6,294,192) is MAINTAINED for reasons of record in the office action mailed 10/18/07 and those set forth below.

II. The rejection of claims 6, 7, 9, 25, and 26 under 35 U.S.C. 103(a) as being unpatentable over Gardella et al (US Patent No. 4,002,718) in view of Patel et al

(US Patent No. 6,294,192) is MAINTAINED for reasons of record in the office action mailed 10/18/07 and those set forth below.

Applicant's arguments may be summarized as follows. (1) Both Patel and Gardella teach an active pharmaceutical ingredient being combined with a carrier and a small amount of solubilizer. The greatest proportion of the combination, pharmaceutical/carrier, is taken up by the carrier. (2) In addition, Applicant asserts that the solubilizing ingredients of Patel and Gardella (i.e., 2-pyrrolidone) are not taught as possible carriers, nor is there the suggestion that they could be used as carriers. (3) Applicant asserts that the claims of the instant invention differ from the cited prior art in that the listed vehicle acts as a carrier of the pharmaceutical ingredient until evaporation. Thus, there is no teaching/suggestion in either Patel or Gardella about achieving a liquid form of the pharmaceutical solution after being ejected from a thermal fluid ejection device onto a substrate which would evaporate very quickly from the substrate. In addition, Applicant asserts that neither Patel nor Gardella teach or suggest that a solubilizing component such as 2-pyrrolidone could be used alone as a vehicle. (4) Applicant asserts that the phrase 'consisting essentially of' used in the claims limits the scope of the claims to the specified material and those that do not materially affect the basic and novel characteristics of the claimed invention.

Applicant's arguments are not persuasive for the following reasons. Gardella et al disclose digoxin in combination with polyvinyl pyrrolidone (column 2, lines 15-22). Patel et al disclose compositions that include a hydrophobic therapeutic agent and a

carrier (see abstract; columns 6-7, bridging paragraph). A possible hydrophobic therapeutic agent is digoxin (column 21, lines 47-67 and column 23, line 65) which is the same as that disclosed in Gardella et al. In addition, it is noted that Patel et al disclose that their carrier may include surfactants, hydrophobic therapeutic agents, and solubilizers (column 27, lines 20-22). Since Patel et al disclose that polyvinyl pyrrolidone and 2-pyrrolidone are amides useful in the pharmaceutical composition (column 25, lines 34 and 37-38) and list them together, a skilled artisan would recognize them as equivalents and be motivated to replace polyvinyl pyrrolidone with 2-pyrrolidone. Thus, it would be obvious to a skilled artisan to generate a pharmaceutical composition having digoxin and 2-pyrrolidone in both Patel et al and Gardella et al. Furthermore, based on the teachings of Patel et al, a carrier system comprising 2-pyrrolidone would be obvious since the document discloses that the carrier may include solubilizers (column 27, lines 20-22). Also, a skilled artisan would recognize that according to MPEP 2112.01 that products of identical chemical composition cannot have mutually exclusive properties. In other words, a chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties Applicant discloses and/or claims are necessarily present. As a result, while Applicant asserts that the solubilizing ingredients of Patel et al and Gardella et al are not taught as possible carrier, if both cited prior art documents render obvious Applicant's elected active agent, digoxin, in combination with 2-pyrrolidone, then the skilled artisan would recognize that if the compositions are physically the same, they must have the same properties and behave the same. Hence, stating that the 2-

pyrrolidone in the instant invention is a carrier and that of the prior art is a solubilizer does not negate that both compositions comprise the same components.

In regards to Applicant's assertion that both Patel and Gardella teach an active pharmaceutical ingredient being combined with a carrier and a small amount of solubilizer and the greatest proportion of the combination, pharmaceutical/carrier (instant invention), is taken up by the carrier is not persuasive for the following reasons. Applicant, Patel et al, and Gardella et al all disclose (or render obvious) a pharmaceutical composition comprising digoxin in combination with 2-pyrrolidone. Applicant's that the 2-pyrrolidone in both Gardella et al and Patel et al has a different function from that of Applicant and states that once an active step occur (e.g., the vehicle is ejection that it substantially evaporates from the substrate upon which it was deposited) that it is present in a small amount. Applicant is reminded that for product claims, active steps do not determine the patentability. For product claims, patentability is based upon the components present (e.g., the vehicle and active agent), not on what happens to the vehicle once it is ejected onto a substrate. Furthermore, Applicant asserts that the cited prior art documents do not disclose or suggest that an liquid form of the pharmaceutical composition is achieved after being ejected from a thermal ejection device. Once again, Applicant is reminded that the elected invention is directed to a product, not a method of use of the product. Thus, active steps which illustrate what happens to the product once it is used for a particular purpose, do not determine patentability of the product itself.

In regards to Applicant's assertions about the phrase 'consisting essentially of' used in the claims limits the scope of the claims to the specified material and those that do not materially affect the basic and novel characteristics of the claimed invention, Applicant is correct. Therefore, since Patel et al disclose that the carrier system may include solubilizers, then, the skilled artisan would recognize that whether or not Patel et al and Gardella et al disclose that the 2-pyrrolidone is a carrier, since Patel et al disclose that the carrier system may contain other components, those 'other' components do not materially affect the basic and novel characteristics of their pharmaceutical compositions. Applicant is respectfully requested to review claim 7 which does not further limit the components present in the pharmaceutical composition. For example, claim 7 contains active steps that set forth what happens to the vehicle when it is ejected from the device, not what additional components are added to the mixture consisting essentially of a vehicle and active pharmaceutical ingredient. Hence, the rejections are deemed proper.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m.. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/D. L. Jones/

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